DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

May 15, 2003

WARNING LETTER
CHI-13-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

James Pettigrew, President
Diagnostic Imaging
501 South McClun Street
Bloomington, IL 61701

Dear Mr. Pettigrew:

On November 19, 2002, a representative from the Food and Drug Administration (FDA) conducted a field test of a certified diagnostic x-ray system which your firm assembled on August 16, 2002, according to Report of Assembly of a Diagnostic X-ray System, Form FDA 2579, # D 678336. This system was tested to determine its compliance with portions of the Performance Standard for Diagnostic X-Ray Equipment (Title 21, Code of Federal Regulations (CFR), Sections 1020.30-32). Diagnostic x-ray equipment are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). This field test, Test ID [redacted] was performed at the following facility:

[redacted]

X-ray Control Manufacturer: [redacted]
X-ray Control Model: [redacted]
Serial Number: [redacted]
Room #: Radiology

Our analysis of the field test data indicates that the system does not comply with the following item of the Performance Standard:

1. The difference between the indicated source to image receptor distance (SID) and the actual SID was measured to be [redacted]

   The performance standard requires that the SID difference be no greater than 2%. 21 CFR Section 1020.31(e)(1).

We request that you, as the responsible assembler, investigate the above noted deviation from the performance standard, in accordance with 21 CFR Sections 1003 and 1004, as follows:

1) If you determine that the deviation and/or defect is caused by improper assembly or installation, you should correct the deviation and/or defect at no charge to the user by either repairing the system, replacing it, or refunding the cost.

2) If you determine that the deviation and/or defect is caused by the factory-based manufacturer, you should notify the manufacturer of the deviation and/or defect and send documentation of such notification to this office.

3) If you can establish that the system is compliant, that the alleged deviation and/or defect does not exist or does not relate to the safety of the product, or is directly attributable to user abuse or lack of maintenance, you may submit such evidence to this office in accordance with 21 CFR 1003.11(a)(3) within 30 working days of receipt of this letter.

You are requested to report the results of your investigation and follow-up actions to this office within 30 working days of receipt of this letter. Your response should include the date that the corrective action was completed and copies of service records and/or other supportive documents. Failure to respond may constitute a violation of the Act, Sections 538(a)(2) and 538(a)(4) of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968).

You should notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to Matthew J. Sienko, Compliance Officer, Food and Drug Administration, 550 West Jackson Blvd, 15th Floor, Chicago, Illinois 60661.

If you have any questions, you should contact Mr. Sienko at (312) 596-4213.

Sincerely,

\s\
Arlyn Baumgarten
District Director